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EXAMINER

SHEINBERG, MONIKA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,072

Applicant(s)

MOYER ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 12-20, 31-62 and 65-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 21-30, 63, 64 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 sheet . 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group II (claims 1-11, 21-30, 63, 64 and 69), directed to a specific combination of DNA sequences – SEQ ID NO: 12, 20-24, 34, 35 and 37 – in the response filed: 09 October 2003 is acknowledged. The traversal is on the ground(s) that the independent claims should be examined without being limited to specific sequences. As seen below, the independent claims have been examined as generic. Only those claims including the elected sequences have been examined in view of the specific combination. Applicants further assert that "it would not be an undue burden to examine claims reciting the individual sequences" once the elected combination of sequences has been searched. This is not found persuasive because applicants have elected Group II which is directed to a specific combination of sequences to be critical to the relationship assessment of the cultivars were as Group I is directed to only one sequence being the critical determinative between the similarity between cultivars. With respect to searching the combination of sequences, examiner stops the search of the sequences once one sequence of the combination is found to be free of the prior, thereby making the combination itself free of the prior art. Therefore each and every sequence of the combination is not searched if for example the first sequence searched is found free of the art. In addition, the size of sequence databases has increased over the past years significantly, thereby presenting a significant burden to search multiple sequences in the sequence databases. If applicants had elected a single sequence that was found free of the prior art, then it would not be a burden to rejoin a specific combination that includes the sequence found to be free of the prior art because the combination including the instant sequence would also be free of the prior art. The requirement is still deemed proper and is therefore made FINAL. Applicants' are reminded to amend the claims to reflect the elected invention.

2. Claims 12-20, 31-62 are 65-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed: 09 October 2003.

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3. Claims 1-69 are pending.
4. Claims 12-20, 31-62 are 65-68 are withdrawn.
5. Claims 1-11, 21-30, 63, 64 and 69 in view of the elected combination of SEQ ID NO: 12, 20-24, 34, 35 and 37; are hereby examined.

Priority

6. The claim for domestic priority to provisional applications 60/220,854 (7/26/2000) and 60/252,206 (11/21/2000) is acknowledged. The priority date of the instant application is thereby: 26 July 2000.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 1-11, 21-30, 64 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Claim 1 is vague and indefinite due to the lack of clarity of the term “assessing” in lines 1 and 8. It is unclear what are the metes and bounds of the parameters that describe ‘assessing a relationship’. Due to the lack of clarity of the term assessment, it is unclear whether the body of the claim accomplishes that which is set forth in the preamble, “a method of assessing the relationship between a poinsettia plant and a known poinsettia cultivar”. As such claim 2 is also rejected due to dependency from claim 1.
10. Claim 1 is vague and indefinite due to the lack of clarity of the method step of ‘assessing the relationship’ due to the lack of clarity of the term “similarities” in line 9. It is unclear as to what the similarities are based on and what is being identified as being present or absent in the similarities. As such claim 2 is also rejected due to dependency from claim 1.
11. Claims 2, 4, 22 and 64 are vague and indefinite due to the lack of clarity of that which is encompassed by the restriction fragments. It is unclear whether the fragments compromise the full sequence of the elected SEQ ID NOs of the claims, or merely a sequence from within the

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sequence of the SEQ ID NOs. As the claim is written, it is unclear how much of the sequence is intended to be within the restriction fragment. If partial sequences are intended, then two nucleotides of the elected SEQ ID NOs encompassed by an otherwise undefined fragment reads on the claim language.

12. Claim 3 is indefinite for failing to recite a final process step, which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. For example, claim 3 is drawn to a method for estimating a genetic relationship, yet the claim recites a final step of generating a profile index value. No correlation between the action of generating the profile index value and estimating the genetic relationship has occurred within method steps. The claims do not set forth the conditions/state when the method has estimated a genetic relationship. As such claims 4-11 are also rejected due to dependency from claim 3.

13. Claim 9 is vague and indefinite due to the lack of clarity in the listed eight primer pairs to be used due to the term “or” in line 6. It is unclear if all the eight primer pairs are to be utilized as the eight primer pairs, or if at least one of the listed primer pairs are to be included as one of the eight primer pairs, whereas the other seven primer pairs or less can be different primer pairs.

14. Claims 10, 11, 27 and 28 are vague and indefinite due to the lack of clarity of the claim language (emphasis added)

“the profile comprises **the number** of restriction fragments that **correspond** to DNA sequences that include the DNA sequences SEQ ID NO[...],” and “[the representative plant profile] comprises **the number** of restriction fragments that **correspond** to DNA sequences that include the DNA sequences SEQ ID NO [...],” (ie. Claim 10 lines 3-4, 10-12); (see also claim 11, lines 5-6).

It is unclear as to what is defined by ‘number’ and how the number ‘corresponds’ to the SEQ ID NOs. Further, it is unclear if these sequences (SEQ ID NOs) are actual limitations of the claim or do the fragment sequences merely have to ‘correspond’ to these sequences in an undefined fashion. Due to the lack of clarity in of the meaning of these terms and their intercorrelation, it is unclear as to what is actually being detected: the length of the fragments wherein the sequence length corresponds to the SEQ ID NOs, thus appearing as the same band on an electrophoresis gel; or the actual sequence content is being detected of the restriction fragment. In the case where the restriction fragment length is being detected, sequence content would be irrelevant once run on a gel for band patterns, which are dependent on sequence length and not content. As

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such, any sequence with an equal number of nucleotides to i.e. SEQ ID NO: 12 would appear as the same band in the electrophoresis gel from which the band pattern is analyzed to create a fingerprint; thus the sequence fragment would be considered to 'correspond' to SEQ ID NO: 12. As such claim 29 is also indefinite due to dependency from claim 28.

15. The terms "similar" (claim 21, line 12) and "dissimilar" (claim 69, line 9) in claims 21 and 69 are a relative term which renders the claims indefinite. The term "similar" and "dissimilar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As such claims 22-30 are also indefinite due to their dependency from claim 21.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. The claims are directed to the utilization of the amplified fragment length polymorphism (AFLP) analysis for determining genetic relationships and diversity amongst poinsettia cultivars.

18. Claims 1-7, 10, 11, 21-24, 27-30, 63, 64 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al. (*HortScience*, 1997) in view of Sukhwinder et al. (*Crop Improvement*, 1998), as defined by Dice (*Ecology*, 1945).

Ling et al. teaches a method of distinguishing genetic relationships and diversity between Poinsettia cultivars, including breeding family 'Freedom' (claim 5). The method utilizes RAPD analysis to distinguish the identities between Poinsettia cultivars in order to "alleviate some of the confusion of cultivar identity associated with morphological characteristics and multiple cultivar registrations" (p. 124, 1st-2nd column). Figure 3 displays the amplified restriction fragments generated by RAPD analysis and figure 1 (and legend) demonstrates the computed cultivar relationships. The collection of RAPD data, or database as required in claim 28, enables the computation of the displayed cultivar relationships both in Figure 1 and 2.

Ling et al. does not teach the AFLP method steps of distinguishing genetic relationship or diversity as required by the claims.

Sukhwinder et al. teaches a method of distinguishing genetic relationships and diversity between Oryza cultivars (rice) utilizing AFLP analysis. In using the AFLP assay, the pattern of a collection of amplified restriction fragments of one plant/cultivar (its fingerprint) is compared to another in order to determine its similarity or dissimilarity to known cultivars (p. 17, figure 1) as required by claim 1. The fragments are generated utilizing restriction enzymes MseI and EcoRI (p. 16, 2nd column, 1st paragraph)(claims 7, 24), which have tetranucleotide and hexanucleotide recognition sites (claims 6, 23). The comparison is based upon a computed similarity coefficient, or 'index value' (claim language) for each comparison to indicate similarity or dissimilarity. The similarity coefficient is taught to be "derived through pair-wise comparison of the genotypes based on the presence or absence of shared polymorphic bands"(p. 18, 1st column, 1st paragraph)(claims 63, 69). Figure 2 demonstrates the Dice coefficient of similarity (claims 3,

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21) amongst multiple rice varieties. [Dice defines the values or scores range from 0 to 1, wherein 0 indicates dissimilarity and 1 indicates similarity (pp. 298-299, bridging paragraph)].

A computer program was utilized to generate the dendrogram of figure 2, which displays the clustered results of the performed method (p. 18, 1st column, 1st paragraph) (claim 30).

Sukhwinder et al. teaches that other fingerprinting methods such as restriction fragment length (RFLP) analysis and random amplified polymorphic DNA (RAPD) assays had been commonly used to discriminate various cultivars, however the new technique of using AFLP “combines reliability and robustness of RFLP and strength of PCR techniques. Sukhwinder et al. teaches that the AFLP technique is considered powerful for genome mapping, genotype identification and phylogenetic studies” (p. 15, 2nd column, 1st paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to improve the Poinsettia cultivar genetic analysis method of Ling et al. and further modify the RAPD procedure used by Ling et al. to the improved method of cultivar analysis using AFLP techniques as per the teachings of Sukhwinder et al. One of ordinary skill in the art would have been motivated to improve the method of genetic analysis used in Ling et al. from RAPD to the AFLP procedure taught by Sukhwinder et al. because Sukhwinder et al. teaches of the advantages of using the AFLP procedure of analyzing genetic relationships and diversity as opposed to RAPD and RFLP. In addition, Sukhwinder et al. motivates the ordinary artisan to use the AFLP technique because Sukhwinder et al. teaches that although other fingerprinting methods such as RFLP and RAPD assays had been commonly used to discriminate various cultivars, the new technique of using AFLP “combines reliability and robustness of RFLP and strength of PCR techniques”. Sukhwinder et al. teaches that the AFLP technique is considered powerful for genome mapping, genotype identification and phylogenetic studies” (p. 15, 2nd column, 1st paragraph).

As the claims fail to set forth in a clear and definite fashion that which makes up the fragments which are a collection of amplified restriction fragments (see section #11; claims 2, 4, 22, 64) and that which makes up the generated profiles which are vaguely based on the restriction fragments (see section #14; claims 10, 11, 27, 29); the method of Poinsettia fingerprint generation taught by Ling et al. in view of the improved cultivar analysis using the AFLP procedure by Sukhwinder et al. encompass the limitations of claims 2, 4, 10, 11, 22, 27,

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29 and 64. With respect to the fragments as discussed in section #11, two nucleotides of the elected SEQ ID NOs are encompassed by an otherwise undefined fragment, i.e. ones in the Poinsettia fingerprints generated by the method of Ling et al. in view of Sukhwinder et al. (using the AFLP techniques), reads on the claim language. With respects to the profiles discussed in section #14 and the interpretation that the detection of the restriction fragments are based upon length, the SEQ ID NOs carry no relevance to the actual detection steps and a number of different fragment lengths would be generated by an ordinary artisan using the method of Ling et al. in view of Sukhwinder et al., which would be identifiable of the cultivar analyzed. Therefore the amplified restriction fragments of Ling et al. specific to Poinsettia cultivars in view of the improved cultivar analysis of AFLP by Sukhwinder et al., further encompass the indefinite limitations of claims 2, 4, 10, 11, 22, 27, 29 and 64.

19. Claims 1-6, 10, 11, 21-23, 27-30, 63, 64 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al. (*HortScience*, 1997), in view of Barker et al. (*Genome*, 1999) as defined by Tullos (Offprint from Palm ME and IH Chapela, eds, 1997).

Ling et al. teaches a method of distinguishing genetic relationships and diversity between Poinsettia cultivars. The method utilizes RAPD analysis to distinguish the identities between poinsettia cultivars in order to “alleviate some of the confusion of cultivar identity associated with morphological characteristics and multiple cultivar registrations” (p. 124, 1st-2nd column). Figure 3 displays the amplified restriction fragments generated by RAPD analysis and figure 1 (and legend) demonstrates the computed cultivar relationships. The collection of RAPD data, or database as require in claim 28, enables the computation of the displayed cultivar relationships both in Figure 1 and 2.

Ling et al. does not teach the AFLP method steps of distinguishing genetic relationship or diversity as required by the claims.

Barker et al. teaches a method of distinguishing genetic relationships and diversity between Salix cultivars (willows) utilizing AFLP and RAPD analysis. The comparison of the band patterns generated by the AFLP assay is carried out by the computation of a similarity coefficient, or ‘index value’ (claim language) for each comparison to indicate similarity or dissimilarity between plants. The similarity index values were generated utilizing the Jaccard

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coefficient (claims 3, 21) based upon the combined data set for total bands in addition to polymorphic bands that were present or absent generated by restriction digests (p. 178, 1st-2nd column)(claim 1). [Tulloss defines the similarities indices such as the Jaccard coefficient has lower and upper bounds wherein the range is from 0 to 1, wherein 0 indicates dissimilarity and 1 indicates similarity (pp. 126 and 129)]. The bands are fragments generated from the restriction enzymes MseI and PstI, which have tetranucleotide and hexanucleotide recognition sites (p. 176, 1st column, 2nd paragraph)(claims 6, 23). A computer program was utilized to generate the dendograms and plots of figures 2 and 3, which displays the clustered results of the performed method (pp. 179-180) (claim 30). In contrast to the problematic results of RAPD analysis, AFLP was demonstrated to be “highly reproducible and highly discriminatory” (p. 178, 2nd column, 2nd paragraph) therefore Baker et al. suggests that although both assays were informative, the AFLP assay “revealed more genetic diversity and discriminated between closely related clones” (p. 182, 1st column, 2nd paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to improve the Poinsettia cultivar genetic analysis method of Ling et al. and further modify the RAPD procedure of Ling et al. to the improved method of cultivar analysis using AFLP techniques as per the teachings of Barker et al. One of ordinary skill in the art would have been motivated to improve the method of genetic analysis used in Ling et al. from RAPD to the AFLP procedure taught by Barker et al. because Barker et al. teaches the advantages of the AFLP method of analyzing genetic relationships and diversity as opposed to RAPD. Barker et al. motivates the ordinary artisan to preferably use AFLP instead of RAPD in determining accurate cultivar identity by demonstrating that although both were informative, the AFLP assay “revealed more genetic diversity and discriminated between closely related clones” (p. 182, 1st column, 2nd paragraph).

As the claims fail to set forth in a clear and definite fashion that which makes up the fragments which are a collection of amplified restriction fragments (see section #11; claims 2, 4, 22, 64) and that which makes up the generated profiles which are vaguely based on the restriction fragments (see section #14; claims 10, 11, 27, 29); the method of Poinsettia fingerprint generation taught by Ling et al. in view of the improved cultivar analysis using the AFLP procedure by Barker et al. encompass the limitations of claims 2, 4, 10, 11, 22, 27, 29 and

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64. With respect to the fragments as discussed in section #11, two nucleotides of the elected SEQ ID NOs are encompassed by an otherwise undefined fragment, i.e. ones in the Poinsettia fingerprints generated by the method of Ling et al. in view of Barker et al (using AFLP techniques) reads on the claim language. With respects to the profiles discussed in section #14, and the interpretation that the detection of the restriction fragments are based upon length, the SEQ ID NOs carry no relevance to the actual detection steps and a number of different fragment lengths would be generated by an ordinary artisan using the method of Ling et al. in view of Baker et al., which would be identifiable of the cultivar analyzed. Therefore the amplified restriction fragments of Ling et al. specific to Poinsettia cultivars in view of the improved cultivar analysis of AFLP by Barker et al., further encompass the indefinite limitations of claims 2, 4, 10, 11, 22, 27, 29 and 64.

20. The specific combination of DNA sequences – SEQ ID NO: 12, 20-24, 34, 35 and 37 – is not taught or suggested in the prior art.

Conclusion

- Claims 1-11, 21-30, 63, 64 and 69 in view of the elected combination of SEQ ID NO: 12, 20-24, 34, 35 and 37.
- Claims 1-11, 21-30, 64 and 69 are rejected under 35 U.S.C. 112, second paragraph.
- Claims 1-7, 10, 11, 21-24, 27-30, 63, 64 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al. in view of Sukhwinder et al., as defined by Dice.
- Claims 1-6, 10, 11, 21-23, 27-30, 63, 64 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Ling et al. in view of Barker et al., as defined by Tullos.

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The central **Fax number is (703) 872-9306**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (571) 272-0749. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Sitton, can be reached at (571) 272-0752. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (571) 272-0518, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 8, 2004
Monika B. Sheinberg
Art Unit 1634

MBS

**JEHANNE SITTON
PRIMARY EXAMINER**

Jehanne Sitton
3/8/04